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10 **UNITED STATES DISTRICT COURT**
11 **NORTHERN DISTRICT OF CALIFORNIA**

13 SYNTHEGO CORPORATION,
14 Plaintiff/Counter-Defendant,
15 v.
16 AGILENT TECHNOLOGIES, INC.,
17 Defendant/Counter-Claimant.
18
19

CASE NO. 5:21-cv-07801-EJD

**DEFENDANT/ COUNTER-
CLAIMANT AGILENT
TECHNOLOGIES, INC.'S
OPPOSITION TO PLAINTIFF
SYNTHEGO CORP.'S MOTION TO
STAY THIS CASE PENDING *INTER
PARTES* REVIEW**

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22 **REDACTED**
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1 **I. INTRODUCTION**

2 Synthego's request for a stay should be denied because of the advanced state of this case,
3 the improbability that the IPRs will simplify matters for trial, and the likelihood that Agilent will
4 suffer irreparable harm if a stay is granted, particularly given the nature of the prior art challenges
5 at issue here, which as Synthego itself acknowledges, are much more amenable to being addressed
6 in view of a full discovery record that is only available in this Court. Staying this case now would
7 result in an unfair tactical advantage because Synthego has refused to respond to discovery but
8 plans to use discovery that it got from Agilent in the IPRs. At a minimum, discovery and claim
9 construction, including the tutorial, should proceed as set forth herein in parallel with the IPR
10 proceedings.

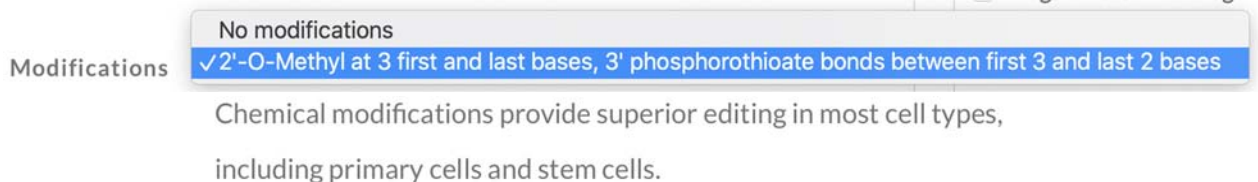
11 This Court already set an expedited schedule in this case in full view of Synthego's IPRs
12 and awareness that institution decisions were due on or before late July. In February, weeks after
13 Synthego's IPRs were filed and brought to the attention of the Court, the Court set an expedited
14 schedule in this case that provides for the completion all fact and expert discovery, as well as
15 summary judgment briefing essentially this year (by January 6, 2023), regardless of whether the
16 IPRs were instituted, thereby clearing the road for trial prior to a Final Written Decision from the
17 PTAB. The Court should proceed to resolve this case on the schedule it already set, even after
18 Synthego filed its IPRs and indicated it intended to seek a stay.

19 The parties are deep into the Court's expedited schedule. The claim construction process
20 is well underway, and both the tutorial, which will provide the Court with additional needed context
21 about this dispute, and the *Markman* hearing, will be completed in August. In its Petitions,
22 Synthego took the position that no claims need to be construed. But here, Synthego took a contrary
23 position, and asserts claim construction on a number of terms, the result of which that may well
24 undermine its Petitions. Infringement and invalidity contentions have been exchanged. Fact
25 discovery closes in ninety days. Expert discovery closes two and a half months later, and summary
26 judgment motions will be briefed in just over six months.

27 Synthego claims that there is much remaining to do in discovery, but it knows that what
28 remains is really its own long over-due compliance with its discovery obligations and/or its decision

1 to serve written discovery requests only recently. But Synthego's failure to meaningfully
 2 participate is no justification for a stay, particularly where Synthego waited eight months to seek
 3 its stay. Agilent, for its part, completed the majority of its document production in February of this
 4 year (95% of the documents produced in this case were produced by Agilent), has offered four
 5 witnesses for deposition, and stands ready to complete its own discovery and provide any additional
 6 discovery that Synthego needs before the close of discovery.

7 Synthego tellingly does not provide any specifics regarding the discovery that remains
 8 because it knows that this case is very straightforward in many ways. The asserted claims are
 9 directed to chemically modified guide RNAs that are functional for the CRISPR system, and
 10 specify a variety of specific chemical modifications at particular locations. Verifying infringement
 11 requires only a straightforward comparison of the sequences that Synthego makes, uses and sells
 12 with the variations of modifications in the claims. And there is no doubt that the modifications are
 13 there. Synthego has admitted that it did not innovate on the chemistry but instead uses at least the
 14 modifications in the Hendel paper, which no one disputes are covered by the claims. Many of the
 15 claimed modifications can be ordered using a drop-down menu on Synthego's website. For
 16 example, this is a drop-down option on the Synthego website:



21 These modifications exactly match the modifications called out in several asserted claims, and even
 22 Synthego boasts of about their functionality. In fact, Synthego did not contest infringement in its
 23 opposition to Agilent's preliminary injunction motion.¹ Once Synthego completes its production
 24 of documents identifying what modifications it has made, used or sold, summary judgment of
 25 infringement should be a straightforward exercise.

26 ¹ Damages are similarly straightforward. Virtually all of Synthego's sales are infringing. Its
 27 business is selling modified guides or using modified guides to engineer cells. Synthego's safe
 28 harbor claims are equally straightforward. For each sale, Synthego can either prove that its guides
 are being used solely for FDA approval, or not. To date, Synthego has not established that a single
 guide is subject to the safe harbor defense found in §271(e)(1).

1 Synthego knows this—and that is why, to date, it has improperly delayed the progress of
 2 this case by redacting from production documents the actual sequences for the guides it has sold—
 3 in particular for larger-scale orders of custom products. And Synthego has been coy about whether
 4 it is withholding other documents revealing custom modified guides. Synthego should be ordered
 5 to produce this information forthwith (regardless of a stay) for two reasons.

6 First, the issue is black and white. Other than to create the impression that little discovery
 7 has been done to support the instant motion in the event its IPRs were granted, Synthego has never
 8 had any basis in the law to withhold documents regarding the sequences of the modified guide
 9 RNA it has sold or to redact information, particularly highly pertinent non-privileged technical and
 10 business information, from documents produced designated as outside counsel under the default
 11 protective order.² This discovery was due in March. After Synthego finally produced a handful of
 12 documents in late April, Agilent asked for fulsome technical documents and unredacted copies³ of
 13 the documents it has produced in writing over a half-dozen times and on multiple meet-and-confer
 14 calls. They should be produced immediately.

15 Second, consistent with PTO statistics, the institution decision confirms that this case will
 16 proceed regardless of the outcome of the IPRs.⁴ Notably, the PTAB’s preliminary opinion indicates
 17 that a number of claims are likely to survive the IPR proceedings. Agilent has recently learned
 18 Synthego infringes one of those claims, claim ■ of the ’034 Patent, even though it is not a standard
 19 modification (“drop-down menu”) option. Agilent is entitled to know now which of the other
 20 claims that the PTAB has indicated will likely emerge from the IPRs that Synthego also practices.
 21 Synthego started this fight, seeking a declaration that it did not infringe. But Synthego has
 22 strategically delayed providing discovery on the very issues presented in its complaint in the hopes

23 ² The parties have agreed to operate under the default protective order and have been doing
 24 so. Agilent also offered to officially enter the default order as the protective order in this case.

25 ³ Minutes before the filing of this reply, Synthego produced documents that an email from
 26 Synthego’s counsel indicates are unredacted copies of documents originally produced in April.
 These documents have not yet been reviewed.

27 ⁴ Although the PTAB institutes 82% of all biotechnology/pharma IPRs, only 17% of total
 28 patents challenged had all claims cancelled. *See* PTAB Outcomes by Patent (FY21: Oct. 1, 2020
 to Sept. 30, 2021), *at*
https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2021__roundup.pdf (slide 12).

1 that the case would get stayed before it was forced to reveal the extent of its infringement. But this
 2 case is at least coming back on '034 claim ■. Agilent is entitled to know the full extent of
 3 Synthego's infringement, particularly of claims that are highly likely to survive—even if the case
 4 is stayed.

5 This Court can and should decide this case on the schedule it already set. Failing to do so
 6 will result in significant prejudice to Agilent. As explained in its preliminary injunction motion
 7 and reply, Agilent is already suffering irreparable harm as Synthego—Agilent's direct and sole
 8 competitor in the full-service gRNA market—continues to willfully infringe Agilent's patents and
 9 erode the price of practicing products. Synthego's proposed stay will further advance Synthego's
 10 plans to permanently disrupt a “game-changer,” multi-billion dollar market with its acquisition of
 11 sticky customers, poaching of Agilent's customers, cut-rate pricing, and decision to increase market
 12 share at the expense of important innovators like Agilent who have invested substantially in
 13 developing ground-breaking technology and securing (what should be) enforceable IP rights. Any
 14 chance that the issues in this case could be simplified if the Court awaits the outcomes of *both* the
 15 PTAB and the Federal Circuit is simply not enough to outweigh the certain prejudice to Agilent,
 16 and the clear tactical advantage to Synthego, if a stay is granted.

17 Separately, there are compelling reasons for this case to proceed in this forum in parallel
 18 with, or in advance of, a PTAB decision in order to avoid giving Synthego an unfair tactical
 19 advantage. *Synthego chose this forum*, and should not be heard to complain about proceeding in
 20 this forum, which has a local interest in this dispute. It is also the only forum in which the fulsome
 21 record that is necessary to decide the invalidity issues can actually be developed. Synthego itself
 22 seeks this Court's assistance in supplementing what is available in IPR proceedings with the
 23 depositions that it took of percipient Agilent witnesses and regarding Agilent documents. That is
 24 because the primary issue with regard to anticipation is whether the Pioneer Hi-Bred reference that
 25 Synthego relies on is enabled.⁵ Agilent bears the burden of proving that Pioneer Hi-Bred is not

26
 27 ⁵ Agilent disagrees with the PTAB's preliminary recitation of the law and more importantly,
 28 interpretation of the facts Agilent set forth in its limited preliminary response. But the PTAB was
 required to resolve all factual inferences in favor of Synthego in making its institution decision, so
 its preliminary decision must be interpreted in that light.

1 enabled, and although enablement is ultimately a question of law, it depends on underlying factual
 2 inquiries into undue experimentation, as articulated in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir.
 3 1988), including: (1) the quantity of experimentation necessary, (2) the amount of direction or
 4 guidance disclosed, (3) the presence or absence of working examples, (4) the nature of the
 5 invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability
 6 in the art, and (8) the breadth of the claims.

7 Critically, the evidence that Synthego seeks to use from Agilent depositions and documents
 8 in this case relates precisely to these factors. *See, e.g.*, Dkt. 90 at 2 (Synthego seeks to unseal
 9 “testimony regarding Agilent’s knowledge of the state of the art of RNA modifications based upon
 10 publicly available publications and prior art during the relevant timeframe” for use in the IPRs.)
 11 But the inquiry is not about what Agilent knew. It is about the state of the art, the predictability of
 12 the art, et cetera. Agilent should be permitted to develop an equal and opposing factual record in
 13 this case, via discovery of Synthego and third parties. Indeed, Agilent has served discovery on
 14 Synthego seeking exactly this information, which Synthego has to date refused to provide—while
 15 at the same time seeking to use the discovery Agilent provided in good faith in accordance with
 16 this Court’s instructions. *See* Dkt. 49 at 2.⁶

17 This case should not be stayed, and instead should proceed on the expedited schedule that
 18 this Court has already set. At a minimum, discovery should not be stayed and the tutorial and claim
 19 construction hearing should proceed because: this case will not be fully resolved by the IPRs; the
 20 terms proposed for construction apply to all claims; the parties are already deep into this process;
 21 Synthego has taken inconsistent positions regarding claim construction that should be resolved;
 22 and even Synthego itself concedes that the record regarding whether Pioneer Hi-Bred is enabling
 23 would be advanced by evidence beyond that which can be obtained in the IPR proceedings.
 24 Because Agilent bears the burden of proof on this issue on whether Pioneer Hi-Bred is enabled, it
 25 surely should be permitted to pursue that discovery in this forum, chosen by Synthego.

26 ⁶ Synthego may contend that it did not enter the market until after the patents were filed,
 27 but it is quite clear that evidence that tends to show unpredictability, for example, that post-dates a
 28 filing is relevant to the enablement inquiry. *See Amgen Inc. et al. v. Sanofi Aventisub LLC et al.*,
 872 F.3d 1367, 1375 (Fed. Cir. 2017).

1 II. LEGAL STANDARD

2 “Courts have ‘no obligation to stay proceedings pending parallel litigation in the PTAB.’”
 3 *Net Fuel, Inc. v. Cisco Systems, Inc.*, No. 5:18-cv-02352-EJD, 2020 WL 836714, at *1 (N.D. Cal.
 4 Feb. 20, 2020) (denying stay after IPR instituted) (*quoting Space Data Corp. v. Alphabet Inc.*, No.
 5 16-cv-03260-BLF, 2019 WL 1131420, at *1 (N.D. Cal. Mar. 12, 2019) (denying stay request after
 6 IPR instituted)). While the “Court ultimately decides whether to issue a stay on a case-by-case
 7 basis,” case law supplies general considerations to consider “when a defendant in a patent
 8 infringement action petitions for IPR and then moves the district court to stay the proceedings,”
 9 including: “(1) the stage of the case; (2) whether a stay will simplify the court proceedings; and (3)
 10 whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving
 11 party.” *Net Fuel*, 2020 WL 836714, at *1 (internal quotation omitted). “In assessing the final
 12 factor—whether a stay will unduly prejudice or tactically disadvantage the nonmoving party—
 13 courts assess four subfactors: ‘(1) the timing of the petition for review; (2) the timing of the
 14 request for the stay; (3) the status of review proceedings; and (4) the relationship of the parties.’”
 15 *Net Fuel*, 2020 WL 836714, at *2 (*quoting Uniloc USA Inc. v. LG Elecs. U.S.A. Inc.*, No. 18-cv-
 16 06737-JST, 2019 WL 1905161, at *5 (N.D. Cal. Apr. 29, 2019)). And here, where the parties are
 17 direct competitors, the nonmovant seeks a preliminary injunction, and the movant is not “a
 18 defendant in a patent infringement action” but instead a plaintiff that timed its declaratory relief
 19 action, timed the IPR filings, and timed this motion to stay, the Court’s case-by-case inquiry is
 20 especially important.

21 III. ARGUMENT

22 A. The Court set this case on an expedited schedule after the IPRs were filed, 23 and the parties are deep into that schedule.

24 Synthego promised a motion to stay in its original complaint on October 5, 2021. But this
 25 case has now progressed substantially in the eight months since Synthego indicated it would move
 26 to stay these proceedings.

27 In the initial Case Management Conference, and after Synthego had already filed its IPRs,
 28 Synthego unsuccessfully tried to convince this Court that Agilent’s motion for preliminary

1 injunction should not be heard until after the PTAB's three-month period for institution had run, in
 2 late July 2022. 1/20/2022 Hr'g. Tr. 11:2-14. Synthego argued that not only would the parties need
 3 to do "at lot of the case work" for that PI, including fact and expert discovery, but also highlighted
 4 this Court's own substantial work required to prepare for the PI hearing. *Id.* But the Court rejected
 5 that request, set this case on an expedited schedule, and as Synthego predicted, a significant amount
 6 of work has been done.

7 For example, Synthego has taken three 30(b)(6) depositions covering six topics, an expert
 8 deposition, and propounded numerous document requests and interrogatories. Agilent has, in turn,
 9 responded to Synthego's discovery requests, produced over 83,000 pages of documents, served a
 10 67-page expert report detailing Synthego's infringement, propounded interrogatories and document
 11 requests, and retained and disclosed both technical and financial experts. Further, the parties have
 12 exchanged infringement contentions, invalidity contentions, damages contentions, and preliminary
 13 claim constructions. Dkt. 51 at 3. By Synthego's admission therefore, the nature of the completed
 14 discovery to prepare for the PI hearing is more burdensome on the parties than the discovery that
 15 remains in this case, and it has been completed. *Cf.* 1/20/2022 Hr'g. Tr. 11:2-14.

16 In addition to the case's accelerated pace thus far, the tutorial and *Markman* hearing is set
 17 for August 31, 2022. Dkt. 51 at 3. Fact discovery will be complete only a month later, on
 18 September 30, 2022, and expert discovery will be finished by December 9, 2022. *Id.* The parties'
 19 dispositive motions will be filed by January 6, 2023; the case can be ready for trial shortly
 20 thereafter. *Id.* at 4. With the case moving apace, and a trial setting conference on September 1,
 21 2022, there is no reason that trial in this action cannot go forward in April 2023. *Id.* at 3. Thus, by
 22 contrast to the expedient resolution that can be achieved in this action initiated by Synthego, any
 23 stay that awaits a binding decision from the PTAB and Federal Circuit would halt Agilent's
 24 enforcement rights against its direct competitor for two to three years. And this would have the
 25 ripple effect of impacting all of Agilent's other enforcement or licensing efforts.

26 There are compelling reasons to proceed with claim construction on the current schedule.
 27 In the IPR proceedings, Synthego contended that no claim construction was necessary. *See* Dkt.
 28 77-3 at PageID 37; Dkt. 77-4 at PageID 35. But in this case, Synthego now argues that three claim

1 terms should be given very specific meanings that could potentially undermine its Petitions. Put
 2 simply, this is more of Synthego’s gamesmanship. Synthego should not be able to take one position
 3 in the IPRs and preserve for itself another position in this proceeding while it is stayed. The Court
 4 can and should decide this now.

5 Aside from contending that not much discovery has been done, it is telling that Synthego
 6 does not identify any particular discovery from Agilent that remains outstanding. That is because
 7 there is little to none. As to Synthego, but for its delays and improper discovery tactics, which
 8 should not inure to its benefit on a motion to stay, Agilent expects that there will be little issue
 9 completing discovery. Agilent already served discovery requests in February; but Synthego has
 10 only produced 195 improperly redacted documents to date. Synthego simply needs to tender
 11 responsive documents, including documents sufficient to show the structures of the modified guide
 12 RNAs that it made, used, or sold (i.e., sequences showing modifications and their locations); sales
 13 and financial information; information regarding its research and development (including
 14 functionality and unpredictability of modifications); and how Synthego itself uses modified guides
 15 in the manufacture of its products and delivery of services to its customers. To the extent that
 16 Synthego wants to establish that any use is covered by the safe harbor, it has had plenty of time to
 17 do that—it was the original basis for Synthego’s complaint last October.

18 More fundamentally, apart from the literal advancements in this proceeding, the real issue
 19 assessed in weighing the first factor is whether the investment by the time of the stay motion is so
 20 substantial that “there will be less benefit and greater risk of prejudice to the other [non-moving]
 21 party.” *Net Fuel*, 2020 WL 836714, at *1 (denying stay after IPR instituted, based on the advanced
 22 stage of the case, despite finding the second factor neutral and the third factor favoring a stay)
 23 (citing *Asetek Holdings v. Cooler Master Co., Ltd.*, No. 13-cv-00457-JST, 2014, WL 1350813, at
 24 *3 (N.D. Cal. Apr. 3, 2014)). Courts like that in *Asetek* acknowledge that where discovery is not
 25 complete and a trial date has not been set, courts are more likely to issue stays, but “[t]hat is because
 26 an early stay may save the parties and the Court the unnecessary expenditure of significant
 27 resources,” whereas “a late stay necessarily produces less benefit and enhances the possibility of
 28 prejudice.” *Asetek Holdings*, 2014 WL 1350813, at *3. Regardless of whether the trial date has

1 been set, therefore, Agilent’s substantial and costly investment in expert and fact discovery, as well
 2 as its substantial motion practice, is not in dispute. And here, where Agilent was brought in as a
 3 defendant to Synthego’s declaratory judgment action months before Synthego’s belatedly filed
 4 IPRs, and where “a lot of the case work” has already been done, the benefits typically achieved by
 5 an “early stay” are attenuated, while the prejudice to Agilent is certain. *See id.*; 1/20/2022 Hr’g.
 6 Tr. 11:2-14.

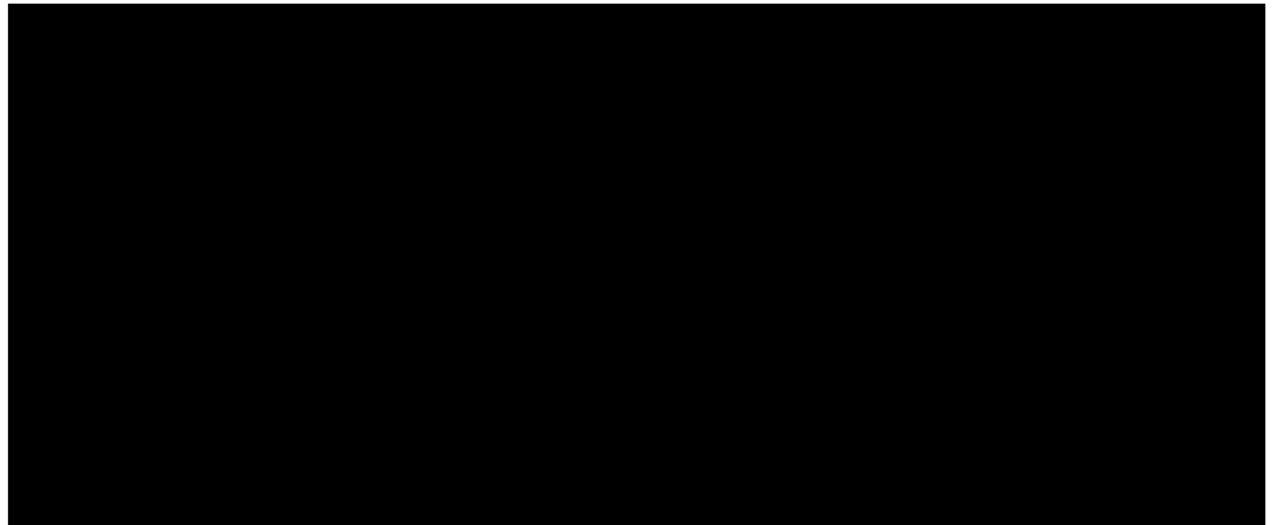
7 **B. The IPRs will not resolve, or even greatly simplify, these proceedings.**

8 Synthego’s motion rests on the faulty assumption that its IPRs will substantially simplify
 9 the issues for this Court to adjudicate and conserve judicial and party resources. But here the PTAB
 10 has already “expressed skepticism” regarding Synthego’s showing of obviousness for various
 11 dependent claims of the ’034 Patent, “e.g., claims 5-13 and 20-28,” and claims 14 and 29 (“ground
 12 six”) (Dkt. 77-1 at 31), as well as “claims 8, 9, 11, 16, 18, 19, 25, and 26” of the ’001 Patent (Dkt.
 13 77-2 at 30-31) in light of “the unpredictability of the effects of RNA modifications on various RNA
 14 or oligonucleotide types.” This is consistent with the PTO’s statistics showing that 82% of the
 15 bio/pharma petitions are granted, but only 17% result of all petitions result in the cancellation of
 16 all challenged claims.

17 Notably, claim [REDACTED] of the ’034 Patent is one of those claims. And although the claim [REDACTED]
 18 modification is not available on a pull-down menu on the Synthego website, Agilent has learned in
 19 discovery that this claim is in fact practiced by Synthego. Dkt. 85-5 (PI Reply Ex. 56) at 1743,
 20 1744, 1745, 1775 (showing [REDACTED]
 21 [REDACTED]). Thus, the case will very likely proceed as to at
 22 least this claim, which implicates all of the claim terms at issue in the claim construction
 23 proceedings, regardless of the outcome of the IPR proceedings.

24 Moreover, there are other claims that Synthego may well practice. In footnote 1 of its
 25 Motion, Synthego suggests that Agilent knows that Synthego does not practice claims 6, 7, 22 and
 26 23 of the ’034 Patent, or claims 8, 11, 16, 19, and 26 of the ’001 Patent because Agilent’s
 27 infringement contentions recite infringement of those claims “on information and belief.” Mtn. at
 28 2, fn. 1. But as with regard to its practice of claim [REDACTED] of the ’034 Patent, Agilent’s contentions are

1 information and belief solely because Synthego does not make all of its product information
 2 (including available custom modifications) publicly available. And in this case, Synthego has
 3 systematically obstructed inquiry into both the nature and locations of modifications associated
 4 with its actual sales—and in particular its sales of customized and non-standard guides—by
 5 redacting that information from all its production documents.⁷ Exhibit 71 to Agilent’s preliminary
 6 injunction reply brief (Dkt. 85-11) (SYNTHEGO-AGI00004065-4079) is instructive:



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 15 To be clear, Synthego applied them to each and every document *as produced in discovery*. While
 16 Synthego finally unredacted certain information from exhibits it submitted with its opposition to
 17 Agilent’s preliminary injunctions motion,⁸ Agilent has been asking for fulsome document
 18 productions, including detailed information about all modifications offered or used by Synthego,
 19 as well as the unredaction of the limited materials that it did produce since at least May 4. *See*
 20 Dkts. 86-4 to 86-7, 93 (PI Reply Exs. 66-69). This obfuscation is not permitted under the Federal
 21 Rules of Civil Procedure. *Live Nation Merch., Inc. v. Miller*, No. 13-CV-03936 CW (NC), 2014
 22 WL 1877912, at *3 (N.D. Cal. May 9, 2014) (ordering reproduction of unredacted version of
 23 documents). If the information that Synthego redacted (or otherwise failed to produce) implicate
 24 claims that the PTAB has already found are not likely to be found invalid, this provides a further

25
 26 ⁷ Synthego has repeatedly pointed Agilent to a single document describing Synthego’s Product
 27 Intake Process, which is also the only document it cited in its P.L.R. 3-4(a) disclosures. Dkt. 86-
 8 (PI Reply Ex. 70) at 35 & Dkt. 85-5 (PI Reply Ex. 56).

28 ⁸ *See also* Dkt. 76-1, Nowatzke Decl., Exs. H, K-O, U, X.

1 compelling reason that Court should not stay this proceeding.

2 Even if all claims are left intact, however, this Court will, by Synthego's own admission,
3 be left to adjudicate "substantial numerous invalidity arguments" not raised in the PTAB. *See, e.g.,*
4 De Mory Decl., Ex. 1 & 2 (Synthego's Replies to Patent Owner's Responses in IPR2022-00402, -
5 00403) at 2 ("The invalidity grounds in the Petition are a mere subset of substantial numerous
6 invalidity arguments Petitioner presents in district court."). Indeed, by the assertions of Synthego's
7 own Complaint, estoppel would do little to streamline a case initiated on safe harbor grounds having
8 nothing to do with the invalidity challenges pursued in the IPRs. Dkt. 1 (alleging non-infringement
9 based *solely* on 35 U.S.C. §271(e)(1)).

10 **C. A stay will prejudice Agilent and result in a clear tactical advantage for**
11 **Synthego.**

12 **1. There are compelling reasons for this case to proceed in this forum.**

13 The PTAB's institution decisions also provide strong support for proceeding in this forum
14 even as to the claims which the PTAB indicated that "at least facially" a prior art reference like
15 Pioneer Hi-Bred (without any disclosure of the claimed functionality, let alone demonstration of
16 operability) "need not disclose test data to support its teaching that the modified crRNAs in Table
17 8 have the recited guide RNA functionality." Dkt. 77-1 at 29; Dkt. 77-2 at 29. The PTAB itself
18 indicated that a more fulsome record will be required for consideration of the petitions. Dkt. 77-1
19 at 29 (noting that "this case is still at a preliminary stage and the record is not fully developed"),
20 31 (discussing need for further factual development on unpredictability); Dkt. 77-2 at 29, 31
21 (same).

22 Notably, one of Agilent's primary contentions regarding Pioneer Hi-Bred is that it is not
23 enabled. To be enabling, a reference must "enable one of ordinary skill in the art to make the
24 invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d
25 1312, 1314 (Fed. Cir. 2008). Determining enablement is a question of law based on underlying
26 factual determinations. *In re Morsa*, 803 F.3d 1374 (Fed. Cir. 2015). The list of factual inquiries
27 relating to whether a person of ordinary skill in the art could make the claimed invention without
28 undue experimentation, as articulated in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), include:

1 (1) the quantity of experimentation necessary, (2) the amount of direction or guidance disclosed,
 2 (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of
 3 the prior art, (6) the relative skill of those in the art, (7) the predictability in the art, and (8) the
 4 breadth of the claims. Agilent bears the burden of overcoming that Pioneer Hi-Bred is presumed
 5 enabled.

6 Synthego pointed to four proposed modification designs in its Petition from Table 8 of
 7 Pioneer Hi-Bred. The PTAB acknowledges that Agilent demonstrated that these included non-
 8 functional designs. This should have been enough. *See, e.g., Forest Labs., Inc. v. Ivax Pharms.,*
 9 *Inc.*, 438 F. Supp. 2d. 479, 486-87 (D. Del. 2006) (“[F]ailures by those skilled in the art (having
 10 possession of the information disclosed by the publication) are strong evidence that the disclosure
 11 of the publication was nonenabling.”) (quoting *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir.
 12 1985)). But in determining whether to institute, the PTAB is required to resolve all factual
 13 disputes in favor of the petitioner, and thus, it is not surprising that the PTAB instituted on the
 14 record before it.

15 Whether resolved in this case or the PTAB, the factual questions presented in the *Wands*
 16 factual questions warrant the complete and fulsome development of a factual record regarding
 17 unpredictability in the art, and whether the alleged invention of Pioneer Hi-Bred does, as Agilent
 18 contends, require undue experimentation. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085
 19 (Fed. Cir. 2008) (holding that the district court correctly concluded prior art lacked enablement
 20 where discovery of the method and combination of variables required was sufficiently uncertain
 21 and arduous as to require undue experimentation). And it is notable that Table 8 on which
 22 Synthego relies contains dozens of additional sequences beyond the four it cites. Third party
 23 discovery relating to the functionality of those additional designs is something that Agilent should
 24 be free to explore.

25 Even Synthego contends that a more fulsome record than will be available in the PTAB is
 26 needed. As Synthego knows, any discovery beyond deposing the opposing expert is disfavored in
 27 the PTAB. *See, e.g.*, 35 U.S.C. § 316(a)(5)(A) (“discovery shall be limited to [] the deposition of
 28 witnesses submitting affidavits or declarations and [] what is otherwise necessary in the interest of

justice”); 37 C.F.R. § 42.51(b)(1)-(2). Thus, Synthego took discovery in this proceeding and has indicated that it intends to use in the PTAB testimony that goes to the very factual issues that must be addressed in the *Wands* factors. Indeed, Synthego filed a separate motion in this Court for the sole purpose of being able to use the discovery it obtained in this case in the IPR proceedings even though the PTAB would never have allowed it to obtain this discovery. Dkt. 83 at 1, 4-5; Dkt. 74-3 at 5-6. Synthego’s insistence that *this Court’s* procedures are essential to determining these complicated issues underscores that *this Court* should decide them, and should do so on the expedited schedule that it already set. And importantly, Synthego has improperly refused to answer reciprocal discovery from Agilent.

Allowing Synthego to stay this case in its current posture would give Synthego a clear strategic advantage. Even as to invalidity issues that Synthego *did* raise in the IPRs, Synthego concedes that discovery in this case—and beyond what is permitted in the PTAB—is critical to a determination of the validity issues presented in its IPRs. Dkt. 83 at 1, 4-5; Dkt. 74-3 at 5-6. Staying this case now would prevent Agilent from getting equivalent discovery from Synthego and other third parties, and reward Synthego for its improper refusal to meaningfully participate in discovery in a case that it filed. Thus, at a minimum, discovery should not be stayed.

2. The substantial prejudice to Agilent outweighs any benefit of a stay, where the parties are direct and sole competitors in the full service gRNA market.

Synthego built its business by copying Agilent’s “landmark” innovations. Synthego has used Agilent’s patented technology to aggressively acquire marketshare in a nascent, fast-growing, multi-billion dollar market. More specifically, Synthego is Agilent’s only U.S. competitor in the full-service gRNA market, across all fields of use. Dkt. 40 at 21-22. Synthego has publicly boasted about poaching Agilent’s customers and invaluable key opinion leaders by offering infringing products to them for lower prices or no cost at all—and did so at an early growth stage in the research use market. *See, e.g.*, Dkt. 41-8 at 3. It is also undisputed that the relevant market is a sticky one, where customers are unlikely to change suppliers—especially as they transition to the purchase of modified gRNAs on a larger scale (and likely larger margin) in the pre-clinical and GMP fields. As set forth in Agilent’s preliminary injunction papers, Synthego’s willful

1 infringement is clear, as it has admitted knowledge of the applications before the patents issued and
 2 copying its use of the patented modifications after learning of them in a “landmark” paper in which
 3 Agilent inventors are named as co-authors. *See* Dkt. 85-10 (6/8/2022 Resp. Rog. 3). Indeed, not
 4 only did [REDACTED]
 5 [REDACTED], a document just produced on June 9 further reveals that he
 6 [REDACTED]
 7 [REDACTED] *Id.* (6/8/2022 Resp. Rog. 3); De Mory Decl., Ex. 3 (2/12/18
 8 Email) (SYNTHEGO-AGI00004815). Synthego’s brash disregard for IP rights is not limited to
 9 Agilent; that same email identifies [REDACTED] of *others* as well.

10 3. Synthego’s forum shopping and delay weighs against granting a stay.

11 By Synthego’s account of events, Synthego should have filed its IPRs at least as early as
 12 June 2021, when “Agilent sent emails to Synthego about its patents, including threatening legal
 13 action.” Dkt. 74-3 at 15. “Courts expect accused infringers to evaluate whether to file, and then to
 14 file, IPR petitions as soon as possible after learning that a patent may be asserted against them.”
 15 *Int’l Test Sols., Inc. v. Mipox Int’l Corp.*, No. 16-cv-00791-RS, 2017 WL 1316549, at *3 (N.D.
 16 Cal. Apr. 10, 2017) (*quoting Asetek Holdings*, 2014 WL 1350813, at *5). Indeed, Synthego could
 17 have initiated *inter partes* review [REDACTED]
 18 [REDACTED] (Dkt. 85-10; De Mory Decl., Ex.
 19 2) and according to Synthego, it has known of the bases for seeking invalidation long before it ever
 20 filed this DJ action. Dkt. 74-3 at 3.

21 Instead, Synthego elected to first invoke the jurisdiction of this Court, knowing full well
 22 the substantial work and deadlines the Local Patent Rules require of litigants and the Court, as well
 23 as the accelerated pace of patent cases proceeding in this District. N.D. Cal. Patent L. R. (2020).
 24 And it did so under what appear to largely false pretenses. Despite being presented with a robust
 25 expert report documenting infringement, Synthego did not contest that it practices the asserted
 26 claims in its opposition to Agilent’s preliminary injunction motion. Moreover, Synthego argued
 27 against the sole other noninfringement contention in its initial complaint: that its customers’
 28 activities are protected by the safe harbor. It is unclear that the safe harbor provision even applies

1 here, but in any event, Synthego has now made clear that the vast majority of its sales are for
2 Research Use Only—and cannot be used to seek FDA approval and cannot fall within the safe
3 harbor exemption. Similarly, Synthego has made clear that post-FDA approval uses of its modified
4 guide RNAs likewise are not subject to the safe harbor. And for the narrow bucket of uses that
5 could potentially be exempt, Synthego did not establish that single sale or use falls within the safe
6 harbor in its opposition to Agilent’s preliminary injunction motion.

7 Synthego complains that Agilent delayed in filing its preliminary injunction motion. But
8 that motion establishes the substantial harm that Synthego’s continued efforts to sell into the GMP
9 market will inflict on Agilent, regardless of Agilent’s offer of a license for the Research Use Only
10 field. In contrast, Synthego has been monitoring [REDACTED]
11 [REDACTED], yet waited to file its IPRs until January
12 of 2022. The timing of Synthego’s IPRs, following its filing of this action, belies the tactical
13 purposes of its stay request and these facts alone merit denial. *See, e.g., Cronos Technologies LLC*
14 *v. Expedia, Inc.*, No. 13-1538-LPS, 2016 WL 1089752, at *2 (D. Del. Mar. 21, 2016) (infringer’s
15 delay in requesting reexamination “results in a situation in which a stay would be unduly prejudicial
16 to [patentee] and would present [patentee] a clear tactical disadvantage”). Here, the timing of
17 Synthego’s pursuit of a parallel proceeding, challenging the validity of patents, months after
18 demanding remedies from this Court having nothing to do with validity, warrants an inference that
19 Synthego “is seeking an inappropriate tactical advantage.” *Id.*

20 **IV. CONCLUSION**

21 The state of this case, the fact that it will continue regardless of the IPR results and can be
22 efficiently and completely resolved by this Court on the expedited schedule already set, and the
23 prejudicial and tactical disadvantage of a stay, all weigh in favor of exercising this Court’s
24 discretion to deny the stay. At a minimum, neither discovery nor claim construction should be
25 stayed, as both will impact the IPR proceedings, as well as the subsequent proceedings in this
26 case, which are ready well underway. Accordingly, Agilent respectfully requests that this Court
27 deny the stay, or at a minimum, allow discovery to proceed as set forth herein.

28

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Respectfully submitted,

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